Section 4: 510(k) Summary

This section includes a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

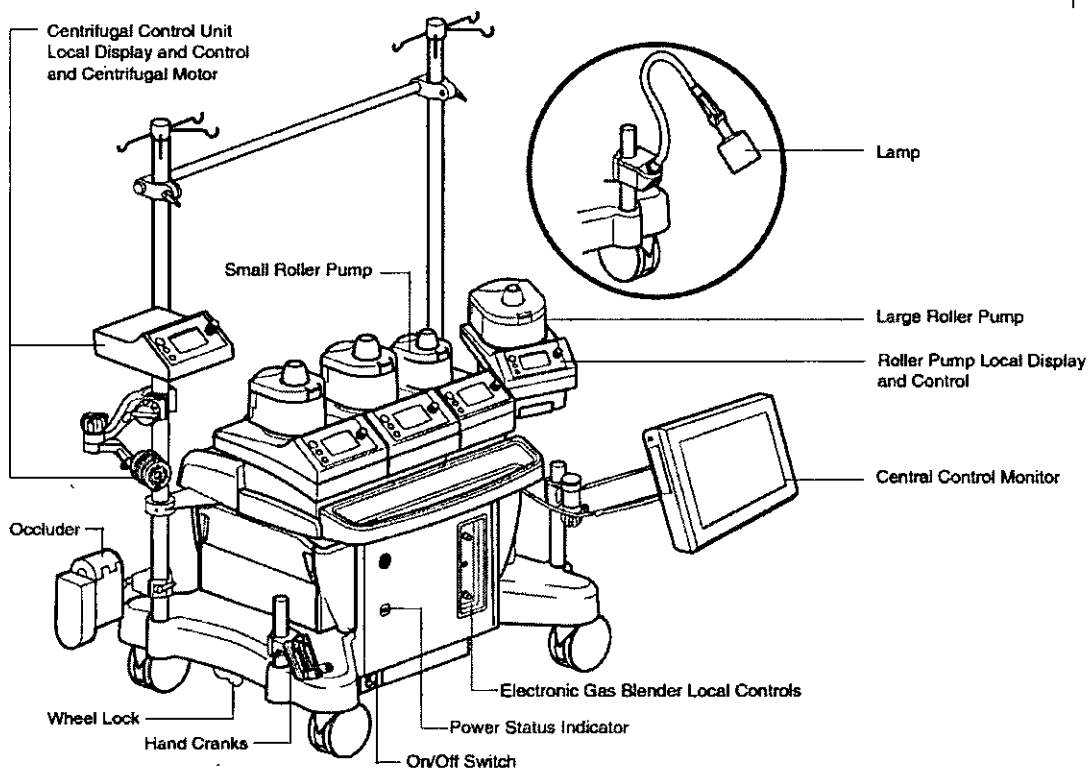
Submitter Information	
Name	Terumo Cardiovascular Systems Corporation (TCVS)
Address	6200 Jackson Road Ann Arbor MI, 48103
Name of Contact Person	Mark Bur
Phone number	Tel: (734) 663-4145
Fax number	Fax: (734) 741-6069
E-mail	Mark.Bur@terumomedical.com
Establishment Registration #	1828100
Date prepared	April 12, 2013
Name of Device	
Trade or proprietary name	Advanced Perfusion System 1
Common or usual name	Heart-Lung Machine
Classification name	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4220
Product Code(s)	DTQ
Legally marketed device(s) to which equivalence is claimed	Advanced Perfusion System 1: K022947 APS1 6" Roller Pump: K112587
Reason for 510(k)	Modifications to previously cleared system and labeling changes

Device Information
Indication for Use: The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment. The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.
Device Description: The Advanced Perfusion System 1 is a configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. The system is designed to enable users to choose from the TCVS supplied components to define and configure a heart-lung system to meet individual institution requirements. The System 1 components are listed below. • System 1 Base: o Chassis platform - Provides operating power and back up battery power for all system components (100/120V or 220/240V) o Central Control Monitor – A touch screen display used for configuration and control of system components o Two roller pump hand cranks and hand crank bracket • Pump(s) and pump mounting hardware – Up to eight pumps can be used with System 1, including the following: o 6" Roller Pump o 4" Roller Pump o Centrifugal Control Module with Centrifugal Drive Motor (up to 2) • Modules o Air Bubble Detection Module - Used to detect air bubbles in the extracorporeal circuit, in conjunction with the air sensor o Level Detection Module - Used to monitor liquid levels within a hard shell reservoir. o Pressure Module – Used to monitor the pressure in the extracorporeal circuit o Temperature Module – Used to monitor the temperature in the extracorporeal circuit and/or the patient o Flowmeter Module – Used to monitor flow volume and generate an alarm if backflow is detected

- Venous Line Occluder Module - Used with the Occluder Head to provide a computer controlled tube clamping mechanism to regulate flow in the venous line
- Interface Modules to enable data transfer between cardiac monitoring and data display systems (e.g., Terumo CDI™ 100 Monitor, CDI™ 500 Monitor, and TLink™ Data Management System)

- Electronic Gas Blender - Provides control and monitoring of the gas output to the oxygenator
- Flexible Lamps (15 inch or 33 inch) for local illumination
- Mounting hardware (e.g., center poles, crossbars, and brackets)

Device Illustration:



Substantial Equivalence

The modified Advanced Perfusion System 1 is substantially equivalent to the currently cleared Advanced Perfusion System 1 because it has the same intended use, substantially equivalent indications for use, and the same or substantially equivalent operating principles and technical specifications. The Advanced Perfusion System 1 has been modified to assure system compliance with the IEC 60601-1-2 electromagnetic compatibility standard, and the Operators Manual has been revised to provide additional warnings and revised instructions for use.

Item	Proposed Device Modified Advanced Perfusion System 1	Predicate Device Advanced Perfusion System 1 (K022947)
Indication for Use	The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment. The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.	The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment. The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

System Components	• System 1 Base with Central Control Monitor and various hardware accessories
	• Large (6") and/or Small (4") Roller Pumps
	• Centrifugal Control Unit and centrifugal drive motor
	• Modules and accessories, including:
	  o Air bubble detector
	  o Level sensor
		• System 1 Base with Central Control Monitor and various hardware accessories
		• Large (6") and/or Small (4") Roller Pumps
		• Centrifugal Control Unit and centrifugal drive motor
		• Modules and accessories, including:
		  o Air bubble detector
		  o Level sensor

Item	Proposed Device Modified Advanced Perfusion System 1	Predicate Device Advanced Perfusion System 1 (K022947)
	o Pressure monitor o Temperature monitor o Flow monitor o Occluder o Electronic Gas Blender o Interface modules for external cardiac and data monitoring systems o Lamp	o Pressure monitor o Temperature monitor o Flow monitor o Occluder o Electronic Gas Blender o Interface modules for external cardiac and data monitoring systems o Lamp
Principles of Operation	Configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. Each component connects to the system network via points on the Base. There are six pump connections, two connections for the CCM, eighteen connections for modules, and two dedicated connections for a lamp.	Configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. Each component connects to the system network via points on the Base. There are six pump connections, two connections for the CCM, eighteen connections for modules, and two dedicated connections for a lamp.
Power Supply	The power system within the Base transforms AC power into the DC levels required by the system components. Integrated batteries provide backup power in the event of AC power loss during use and when power needed exceeds power available.	The power system within the Base transforms AC power into the DC levels required by the system components. Integrated batteries provide backup power in the event of AC power loss during use and when power needed exceeds power available.

Performance Testing

Third party testing was conducted to confirm that, with the engineering modifications in place, the System 1 complies with IEC 60601-1 and IEC 60601-1-2.

Software verficiation and validation testing was conducted for those modules that have undergone software modification since initial clearance.

Moreover functionality testing was conducted on those new or modified components of the Advanced Perfusion System 1 to demonstrate performance compatibility.

All software and performance testing was successful.

Conclusion
The modified Advanced Perfusion System 1 is substantially equivalent to the currently marketed Advanced Perfusion System 1 because it has the same intended use and substantially equivalent performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

Terumo Cardiovascular Systems Corporation
Mark Bur, Regulatory Affairs Manager
6200 Jackson Road
Ann Arbor, MI 48103

Re: K131041
Trade Name: Advanced Perfusion System 1
Regulation Number: 21 CFR 870.4220
Regulation Name: CPB Heart Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: January 27, 2014
Received: January 30, 2014

Dear Mr. Bur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Indication for Use

510(k) Number: K131041

Device Name: Advanced Perfusion System 1

Indications for Use:

The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)